

REMARKS

Independent Claims 1-11 and 34-53 were previously canceled without prejudice to the filing of continuation and divisional applications. Claims 12, 55- 57 are amended to indicate that the polymer in the melt-blend mixture is consisting of a polyurethane polymer. Support for the amendment can be found throughout the specification, e.g., the original claims and the examples. Claims 55-57 are also amended to point out that polyurethane polymer is a polyether polyurethane. Claims 12, and 56- 57 are amended to take out the word "even". Support for the amendment can be found, for example, in the original claims. The "consisting essentially" language has also been taken from claims 12 and 55. Support for the amendment can be found in the application, for example, in the original claims. Claims 56 and 57 are amended to take out the reference to permeation enhancer to make the claims less cluttered. Support for the amendment can be found in the specification, for example, in the original claims. Claim 57 is amended to indicate that the polyurethane polymer is 75 to 95 wt% of the reservoir. New claims 58-59 are added indicating that polyurethane polymer is 75 to 95 wt% of the reservoir. Support for the amendment and new claims can be found, for example, in the specification on page 16, lines 15-16. Claim 15 has been amended, and new claims 58-60 are added to include language referring that the polyurethane can be melt blended with a drug starting from solid or granule. Support for the amendment can be found in the application, in the examples. Claim 61 has been added to indicate that the polymer is polymeric carrier of the drug. Support of the new claim can be found throughout the specification, e.g., on page 2, line 8 of the specification. Since we are disclosing melt-blended mixture to replace solvent cast drug carrying carrier polymer, it is clear that there is support for the amendment. No new matter is added in the amendments and new claims. Claims 12-33 and 54-61 are pending.

Interview Summary

Applicants note with appreciation the courtesy extended to Applicants' attorney, Philip Yip, in the telephone interviews of June 5, 2006 and July 13. During the 6/5 interview, prior art references were discussed. The Examiner also indicated that the office action is not final rejection. Applicants' Attorney pointed out that cited references did not teach the claimed invention. Applicants' Attorney also proposed deleting "consisting essentially of" to go back to the original language of polyurethane polymer. There was also discussion on whether "even if"

has support. No agreement on allowable claim was reached. During the 7/13 interview, the removal of the “consisting essential of” was discussed. The Examiner suggested using the “consisting of” wording to describe the polymer in the reservoir to indicate that the polymer is different from copolymers such as those of Sweet. The US4840796 Sweet reference was discussed. No definite agreement on allowability of individual claims was reached.

35 USC §112 Rejection

§112 first paragraph

The Examiner rejected claim 12-33 54, and 55 under §112 first paragraph as failing to comply with the written description requirement in that the specification does not support 1) “melt blendable polymer”, 2) and “polymer consisting essentially of polyurethane”, and 3) “even without organic solvent”.

In view of the Examiner’s suggestion that we use the term “consisting of”, Applicants have amended the claims accordingly. Applicants respectfully submit that since the specification describes the reservoir as containing polyurethane and in some other passages that the polymer is polyurethane (e.g., in the examples), it is clear to one skilled in the art that Applicants have disclosed the polymer can consist of polyurethane. To move the application forward, Applicants have amended the claim to remove the “consisting essentially of” language. Instead, Applicants have rephrased the claims to indicate that in the melt-blended mixture the polymer is consisting of polyurethane polymer as the Examiner suggested. However, it is understood that the possibility of de minimus presence of other nonpolyurethane polymeric material in the polymer is contemplated and would not avoid the claim.

Regarding “melt blendable polymer”, Applicants submit that since the polymer can be placed in a blender and melted with the blender in action, it is melt blendable. If we disclose the polymer is “melt blendable with a drug”, the polymer is melt blendable, even with itself. Nevertheless, to move the application forward, Applicants have amended the claim to return to reciting that polymer is melt blendable with drug.

Regarding “even without an organic solvent”, it is inherent. Applicants have disclosed that blending can be done with solvent and that in the invention the polyurethane can be melt blended with drug. Thus, anybody will know that we have disclosed that the polyurethane can be blended with drug even without an organic solvent. If I say “I will eat dessert when I am

hungry and I will eat dessert when I am full”, it means I will eat dessert even when I am full. Nevertheless, to move the application forward, Applicants have amended the claim to delete “even without”. Withdrawal of the rejection is requested.

§112 second paragraph

The Examiner rejected claim 12-33, and 54-57 under §112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which we claim regarding the invention in that the claims are omitting steps. Applicants submit that one skilled in the art will know what is being claimed.

The Examiner asserted that the claims are omitting essential steps. But the pending claims are not method claims, rather they are device claims. The Examiner asserted that some steps need to be recited related to the melt blended mixture be used for drug reservoir or rate controlling membrane. However, Applicants clearly stated in the claims that the reservoir comprises the melt blended material. Nothing needs to be said about a rate controlling membrane. The standard for the second paragraph of §112 has long been established as being “reasonable clarity” when read in light of the specification. For instance, in *In re Moore et al.*, 169 USPQ 236, 238 (CCPA1971), the court explained: “This first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.” Based on the clear description in the specification, a person skilled in the art will have no trouble understanding what is being claimed.

Withdrawal of the rejection is respectfully requested.

35 USC §102 Rejection

The Examiner rejected claims 12-14, 20, 22, and 54 under 35 USC 102 as being anticipated by US4840796 (“796 Sweet”). Insofar as the Examiner maintains the rejection over the amended claims, Applicants respectfully traverse the rejection. The Examiner asserted that in Sweet the matrix is made of polyurethane polymer having low melting point. However, the copolymer in Sweet is not really a polyurethane, but rather is a copolymer of a hard segment and

soft segment containing siloxane such as polydiorganosiloxane (see, column 2, line 59-60). In fact, as the examples show, the amount of hard segment having polyurethane material in the copolymer is only 1 to 20% (column 3, lines 40-43 and column 4, line 32-33). No wonder its melting point is low. Nobody skilled in the art will call the copolymer polyether polyurethane, since most of the copolymer is not polyurethane but rather is polydiorganosiloxane or polydimethylsiloxane. In fact, Sweet refers to the polymers in Tables I, II and III in the Examples as "thermoplastic silicones". By analogy, if a house is made with 1-20% brick and the rest of made of wood, nobody will call the house a brick house, but rather people would call it a wooden house.

In view of the fact that the claims have been amend to recite that the polymer is consisting of polyurethane polymer, it is make even more clear that Sweet is entirely inappropriate as prior art. Withdrawal of the rejection is respectfully requested.

The Examiner rejected claims 12-13, 15-20, 22, 23, and 54 under 35 USC 103 as being anticipated by US4638043 ('043 Szycher). Withdrawal of the rejection is respectfully requested. The Examiner asserted that Szycher discloses polyurethane polymer that is liquid at room temperature to facilitate admixture of drug to form a blend and therefore implies the melt temperature of the polyurethane is below 100°C. The Examiner further mentioned that Szycher disclosed TECOFLEX. Applicants submit that the Examiner misreads Szycher.

It is submitted that Szycher mixes PRECURED pre-polymeric liquid at room temperature (see column 2, lines 42-47), not the polymerized polymer. The PRECURED polymeric liquid is not cured and therefore is not polyurethane. Szycher states clearly that the drug dispensing member is comprised of "a polyurethane formed from an oligomer which is cured by actinic radiation....", the drug is incorporated in the material before the material is cured (Column 4, lines 10-14). The polyurethane is *formed from an oligomer by curing*, and is therefore not yet polymerized into polyurethane. Curing changes the thermal and mechanical property of a material, due to cross-link in the curing reaction. Any person skilled in the art will know that such UV-cured polymers cannot be melt-blended. UV curing is an irreversible chemical reaction. Once cured, the material cannot be uncured. Thus, the polyurethane in the UV-cured material cannot be melt-blended anymore. On the other hand, the precured liquid material cannot be melt-blended either, since it being already a liquid cannot melt. Just because something can be mixed in room temperature does not mean it can be melt-blended. By analogy,

concrete mix before setting can be mixed in room temperature. That does not mean the concrete mix is concrete, nor does it mean that concrete after setting can be mixed. Certainly concrete mix, although mixable in room temperature, is not considered to be melt-blendable by one skilled in the art. When we talk about melt blending we mean melting the polymer enough to blend with the drug, not mixing a pre-polymer material before the polymerization takes place. There is no curing after melt-blending in the present invention.

Further, contrary to the assertion of the Examiner, the mention of TECOFLEX by Szycher is NOT on the drug containing layer 16, but rather it is about the SUBSTRATE 12 (see column 4 line 55 to column 5 line 15), which supports the drug containing layer 16. This fact further indicates Szycher never intends TECOFLEX to be used in the drug containing layer. If he bothers to mention TECOFLEX already, why would he not indicate that it could be used for the drug-containing layer if he had thought it practical for such use? For analogy, if in describing a table someone says glass can be used for making the table top (but says nothing about its appropriateness for making the legs) whereas he describes the legs as being made of steel, obviously nobody would think that he teaches using glass for making table legs. The undersigned attorney has seen many tables with glass tops and steel legs, but has yet to see a table with glass legs. Thus, the Examiner's assertion is purely based on hindsight gleaned from our application.

Withdrawal of the rejection is respectfully requested.

35 USC §103 Rejection

The Examiner rejected claims 12-20, 22, 33, and 54 under 35 USC 103 as being unpatentable over US4638043 ('043, Szycher). Insofar as the Examiner maintains the rejection over the amended claims, Applicants respectfully traverse the rejection.

The Examiner asserted that '043 discloses a drug containing polyurethane layer and pressure sensitive adhesive layer and that a drug and permeation enhancer are blended into the polyurethane layer, etc., and that the reference teaches the same polymer formed from the same polymer reaction. Applicants submit the reference does not teach the same polymer at all. Not all polyurethane are the same and certainly not all matrixes containing polyurethane are the same. As previously mentioned, Szycher talks only about UNCURED material as far as mixing or blending is concerned. He never mentions that the cured material can be mixed, regardless of

temperature. He never mentions that the polyurethane layer is liquid at room temperature, only that the precured material is liquid (which is not suitable for a matrix layer in the device because as a liquid it would flow). The Examiner asserted a person skilled in the art would be motivated to adjust the temperature required to melt the polymer to mix the drug. But since Szycher mixes the drug in the pre-polymer in the liquid uncured state, there is no teaching or suggestion about melting or finding a temperature for mixing at all.

Withdrawal of the rejection is respectfully requested.

The Examiner rejected claims 12-33, 54-57 under 35 USC 103 as being unpatentable over US4638043 in view of US5273757('757 Jaeger). Insofar as the Examiner maintains the rejection over the amended claims, Applicants respectfully traverse the rejection.

The irrelevance of US4638043 has been discussed above. Jaeger does not cure the shortcomings of '043. The Examiner asserted that specific drugs, permeation enhancers and acrylate adhesive do not impart patentability to the claims. However, different drugs and ingredients affect the temperature tolerance as well as the physical property of the drug containing layer. Nevertheless, an important difference about '757 is that it teaches that the "pressure sensitive adhesive can contain only up to 10 to 50% by weight of polyurethane" (see column 6, lines 12-13). There are a lot of other soft, semisolid, perhaps liquid material in the adhesive, such as hydrogenated alcohol, hydrocarbon resin, fillers, etc., which can help the material to flow. With mostly non-polyurethane in the adhesive, and so much soft material present, the material is in reality not polyurethane. Jaeger only states that the pressure sensitive adhesive has a processing temperature of 40 – 80 °C (see e.g., column 2 lines 50-51). But Jaeger does not say that the polyurethane has a processing temperature of 40 – 80 °C. There is a difference between the adhesive and its polyurethane ingredient, they are not one and the same. There is no indication that the polyurethane used by Jaeger has a processing temperature of 40 – 80 °C. The pressure sensitive adhesive could have been made with organic solvent to start with to incorporate the hydrogenated alcohol, fillers, etc. Even if one were assumed to want to try, there is not expectation of success that polyurethane without the 50% or more of soft material can be processed at that temperature range. Thus, even if assuming one would want the advantages of lower temperature processing and fentanyl and enhancers, one would not glean

from Jaeger that polyurethane can be processed at a low temperature, only that an adhesive already containing mostly soft material can be processed at a temperature of 40 – 80 °C.

Thus, it is not obvious at all that the polyurethane with processing temperature of less than 150°C is present in the adhesive in Jaeger. Although the Examiner asserted that Jaeger disclosed 10% to 100% polyurethane, Applicants submit that the Examiner misreads Jaeger. It is noted that Jaeger when mentioning 10% to 100% (see column 5, lines 33-44) does not specifically refer to polyurethane but generally refers to a range that some combinations of drug and adhesive could fall into. There is no working examples at all relating to temperature and polyurethane content. A person skilled in the art will certainly understand that not all drugs and adhesives have the same properties and would all be applicable in that range. It is clear to one skilled in the art that not all of the half-a-column-long list of polymers can all be at 100% of the polymer and yet melt blendable at 40 °C, but rather, only certain selected polymer at a certain percentage would have the low temperature property. It could well be only a 10% of a low melting polymer would make an adhesive melt blendable at 40 °C. Further, Jaeger later specifically stated the polyurethane-containing “pressure sensitive adhesive can contain only up to 10 to 50% by weight of polyurethane” (see column 6, lines 12-13). If the adhesive “can contain only up to 10 to 50%”, the meaning has to be that it cannot contain any more than that percentage. Thus, Jaeger is saying that the 10 to 100% may be applicable for some other materials, but anything more than this range is not practical for polyurethane.

Further, in independent claim 57 and in newly added dependent claim 58-59, we have specifically stated that the drug reservoir has 75-95wt% of polyurethane, which is much more than possible with the Jaeger adhesive.

Withdrawal of the rejection is respectfully requested.

The Examiner rejected claims 21, 28, 29, and 32 under 35 USC 103 as being unpatentable over US4638043 in view of US5273757 ('757 Jaeger) and further in view of US6139866 ('866 Chono). Insofar as the Examiner maintains the rejection over the amended claims, Applicants respectfully traverse the rejection.

The irrelevance of US4638043 and US5273757 has been discussed above. Chono does not cure the shortcomings of '043 and '757. The Examiner asserted that Chono discloses formulations comprising fentanyl, acrylate adhesive, permeation enhancers, etc. However, it is

noted that Chono does not mention polyurethane for the drug layer at all. Where Chono mentions polyurethane, he only refers to the backing layer (column 5, line 43-44). Thus, Chono never intends polyurethane to be used in the drug layer, but only for the backing layer. Further, the adhesive layer with the drug is apparently made with solvent (column 5, lines 24-35), perhaps also in high temperature. In all the examples the drug layer is made with solvent and apparently at 180°C. Thus, although the Chono patent discloses fentanyl and certain permeation enhancers, it certainly is irrelevant for melt-blending with drug at a low temperature using a polyurethane polymer that can be processed at or below 150 °C. Chono apparently thinks of polyurethane as unsuitable for holding the drug and enhancers. Even if one were assumed to want to combine Chono with the other references, one would only use fentanyl, enhancers for non-polyurethane reservoir and only use polyurethane for the backing.

Withdrawal of the rejection is respectfully requested.

Claims 21, 28, and 30 are rejected under 35 USC 103 (a) as being unpatentable over US4638043 in view of US5273757 ('757 Jacger) and further in view of US5066648 ('648 Alexander). Insofar as the Examiner maintains the rejection over the amended claims, Applicants respectfully traverse the rejection.

The irrelevance of US4638043 and US5273757 has been discussed above. Alexander does not cure the shortcomings of '043 and '757. The Examiner asserted that Alexander teaches pyroglutamic acid esters as permeation enhancers and therefore one skilled in the art will be led to deliver fentanyl with the enhancers in our claimed invention. However, anybody skilled in the art knows that permeation enhancers do not function the same way for different drugs in different matrixes. An enhancer that works for drug A may not work for drug B in the same polymer. Further, an enhancer that works in a polymeric matrix may not work in another polymeric matrix. Alexander does not mention fentanyl, and does not mention polyurethane as the drug layer carrier polymer. Furthermore, Alexander has nothing to do with melt-blending. Thus, a person skilled in the art will not look to Alexander for suggestions on melt-blending of fentanyl in polyurethane at all. Even if one is assumed for argument's sake to look for guidance at Alexander, there is no expectation of success.

Withdrawal of the rejection is respectfully requested.

The Examiner rejected claims 32 under 35 USC 103(a) as being unpatentable over US4638043 in view of US5273757 ('757 Jaeger) and further in view of US5599289 (289 Castellana). Insofar as the Examiner maintains the rejection over the amended claims, Applicants respectfully traverse the rejection.

The irrelevance of US4638043 and US5273757 has been discussed above. Castellana does not cure the shortcomings of '043 and '757. The Examiner asserted that Castellana teaches wound dressing comprising skin contact acrylate adhesive layer and therefore one would make the presently claimed invention. However, There is no description by Castellana that another polymer is used as an adhesive on a drug reservoir having a different polymer, much less having an acrylate adhesive on a polyurethane reservoir. Thus, the use of acrylate adhesive by Castellana is entirely different from what is claimed. A polymer to be used as a drug reservoir by itself may not be suitable for use to be placed on another reservoir drug layer with a different polymer. In this claimed structure, the drug has to pass from the polyurethane reservoir into the acrylate adhesive before reaching the skin. Castellana does not teach that and there is no expectation of success from Castellana even if one were assumed to want to try.

There is also no mention of fentanyl.

Furthermore, there is no mention of melt mixing temperature and thus Castellana is far removed from the presently claimed invention. What adhesive that works for one drug may not work for another drug. Even less predictable is the combination of two different adhesive layers through which the drug has to migrate.

Withdrawal of the rejections is respectfully requested.

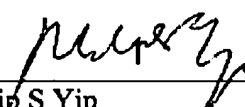
CONCLUSION

Applicants submit the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC 112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

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